510(k) Summary MyLabSix Esaote Europe JUL 1 1 2014

K141486 Page 10f4

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Esaote Europe B.V. Philipsweg I 6227 AJ Maastricht The Netherlands

Contact Person:

Allison Scott, RAC 317.228.8719 Office 317.372.0276 Mobile allison.scott@navigant.com

Date:

January 20, 2014

807.92(a)(2)

Trade Name:

MyLabSix Ultrasound System

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulse Doppler imaging system
Ultrasonic pulsed echo imaging system
Diagnostic ultrasonic transducer

892.1560
892.1570

Classification Number:

901YN, 901YO, 901TX

510(k) Summary MyLabSix Esaote Europe

807.92(a)(3)

Predicate Device(s)

K111302, K132231 and K132466	MyLabSeven	Esaote SpA
•		
K083882	MyLabFive	Esante Europe B.V.

Additional substantial equivalence information is provided in the following substantial equivalence comparison table.

Device Description

The MyLabSix is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Amplitude Doppler (AD), Tissue Enhancement Imaging (TEI), XView, Multi View (MView), Trapezoidal View (TP View), Tissue Velocity Mapping (TVM), RF-based Quality Intima Media Thickness (QIMT), Color Flow Mapping (CFM) and Pulse Wave Doppler.

The MyLabSix is equipped with a free orientable LCD Color Display were acquired images and advanced images are shown.

A second LCD Display for additional controls and mode-depending keys, includes touch screen technology and is integrated in the control panel.

The MyLabSix can drive phased (PA), convex (CA), linear array (LA) probes, Doppler probes and Volumetric probes.

The MyLabSix is equipped with an internal Hard Disk and with an DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (Hard-Disk, PC, server) via a LAN/USB port.

The MyLabSix is manufactured under an ISO 9001:2008 and ISO 13485:2003 certified quality system.

510(k) Summary MyLabSix Esaote Europe

807.92(a)(5)

Intended Use(s)

Esaote's MyLabSix ultrasound system is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

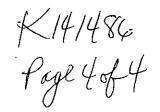
807.92(a)(6)

Technological Characteristics

Esaote Europe B.V. believes that the MyLabSix is substantial equivalent to Esaote's MyLabSeven product (K111302, K132231 and K132466) and Esaote's MyLabFive (K083882).

- Clinical uses for which the MyLabSix is designed are equivalent to those cleared for Esaote's MyLabSeven and MyLabFive.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive are designed to meet the IEC60601-1 and the IEC60601-2-37 safety requirements.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive provides an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive provides a similar measurements and analysis package, with equal accuracy and precision.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive have a digital storage capabilities, including Network connectivity.
- The MyLabSix image modes are available on other FDA cleared ultrasound systems, for instance Esaote's MyLabSeven and Esaote's MyLabFive.

510(k) Summary MyLabSix Esaote Europe 807.92(b)(1)



Summary of Non-Clinical Tests

The MyLabSix has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-37
- NEMA UD-3 Standard for Real time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The MyLabSix is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

Esaote Europe B.V. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

July 11, 2014

Re: K141486

Trade/Device Name: MyLabSix Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, ITX

Dated: June 5, 2014 Received: June 9, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLabSix Ultrasound System, as described in your premarket notification:

	Transducer Model Number	Г
AC2541	SC3421	SC3123
SE3123	AL2442	SL3332
SL1543	SL3323	SL3235
SP2730	S2MCW	S5MCW
SHFCW	SB2C41	ST2612
ЮТ342		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Director

Division of Radiological Health Office of In Vitro Diagnostics

and Radiological Health

Michael D. O'Hara for

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on last page.

510(k) Number (if known)	
K141486	
Device Name MyLabSix Ultrasound System	
Indications for Use (Describe)	
Esaote's MyLabSix ultrasound system is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, I'etal, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as we as peripheral nerve blocks in Musculoskeletal applications.	·
Type of Use (Select one or both, as applicable)	
	er Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEP	ARATE PAGE IF NEEDED.
FOR FDA USE ONLY	
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	
Michael D. OHara	

6420

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	æ	×	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Z	N	ĸ	R	N	X	R		Z	5,7
Abdominal	Z	×	Z	z	×	z	Z		Z	5.7
Intraoperative (Abdominal)	2	N	×		N	Z	N		N	S
Intraoperative Neurological										
Pediatric	z	X	Z		N	Z	N		Z	5
Small Organs [1]	Z	М	z		Z	Z	R		N	S
Neonatal Cephalic	Z	×	Z	2	N	z	N		N	2.
Adult Cephalic	×	×	N	z	N	z	N		М	5
Cardiac [2]	z	z	Z	Z	×	z	N	Z	Z	3
Transesophageal (Cardiac)	z	×	z	Z	Z	z	Z	Z	Z	ιń
Transceophageal (Non Cardiac)										
Transrectal	2	z	Z		×	Z	z		N	2
Transvaginal	z	N	Z		Z	Z	Z		N	s
Transurethral										
Intravascular										
Peripheral Vascular	2	N	2	Z	Z	×	×		N	s
Laparoscopic										
Musculo-skeletal Conventional [3]	Z	z	R		N	Z,	N		Z	s
Musculo-skeletal Superficial [3]	N	R	æ		N	Z	M		N	10
Other (Urological)	N	¥	×		Z	Z	Z		z	5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E.

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D Concurrence of Center for Devices and Radiological Health (CDRH)

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^[1] Small Organs includes Breast, Thyroid and Testicles

^[2] Cardiac is Adult and Pediatric

⁽³⁾ Musculo Skeletal - Nerve Block

^[4] Combined modes are: B+M+PW+CW+CFM+PD

^[5] Compound Imaging (Mview)
[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

1 AC2541 2 SC3421 3 SC3123 4 SE3123 5 AL2442 6 SL3332 7 SL1543 8 SL3323 9 SL3235 10 SP2730 11 \$2MCW 12 S5MCW 13 **SHFCW** 14 SB2C41 15 ST2612 16 **IOT342**

						Mode of Operations	rations			
Claical Application	æ	ī	O.M.O	CWD	Color Doppkr	Amplitude Dappler	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
						QX.				
Ophthalmic										
Fesal	4	a.	4		2	۵	4		•	\$
Abdominat	4	d	d		4	۵	۵		4	5
Intraoperative (Abdommal)									,	
Intraoperative Neurological										
Pediatric										
Smell Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transcaophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethrol										
Intravascular										
Peripheral Vascular	d	4	d		Ь	l	.			5
Laparoscopic										
Munculo-skeletal Conventional	2	d	a		F	۵	a.		8.	
Museulo-akrietal Superticial [3]	d	ā.	•		8.	đ	٨		4	s
Other (Urolugual)	•	•	4		4		d		4	\$

The AC2541 probe is dready cleared via X132466

N: New indication; P: Previously cleared by FDA; E.Added under Appendix E. [1] Small Organs includes Breax, Thyroid and Testicles.
[2] Cardiac is Adult and Pediatric.
[3] Musculo Stefand. There Block.
[4] Combined model are: B-M-77W-CFM+PD.
[5] Computed Integral, Phytical.
[6] Includes contrast (CAT) in Adult Cardiac for left ventricle opacification and visualization of the left tenticular endocardial border.

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SC3421

										-
						Mode of Operations	erations			
Clinical Application	ස	¥	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined 4	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Orper (specify)
Ophthalmic										i
Fetal	۵		۵		Ь	a.	a.		4	'n
Abdominal	۵	۵	۵		۵	Ь	ß.		4	ç
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	a.	ė.	<u>a</u>		a	۵	ے		Ь	5
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardine)										
Transesophageal (Non Cardiac)										
Transfectal										
Transvagnal										
Transurethral		L								
Intravascular										
Peripheral Vascular	٩	ď	d		d	Н	4		d	ē
Laparoscopir										
Musculo-skeletal Conventional	۵	Δ.	۵.		ď	d	<u>s</u>		ه	£
Musculo-skeletal Superficial [3]	۵	α.	۵		d	d	Ġ		d	ē
Other (Urological)	a.	۵	ů.		d	۵	4		Ь	Š
The SC3421 probe is afready										

The SC3421 probe is already cleared via K101605

N. New indication; P. Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

|5| Compound Imaging (Mview) |6| Includes contrast (Cn?t) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border |7| 3D/41)

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MyLabSix Ultrasound System

Esaote Europe B.V.

SC3123

						Mode of Operations	STATION &			
Chalcal Application	8	Z	OMd	CWD	Color		Combined			Other (specify)
					Doppler	Doppler (AD)	₹	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	Z	×	N		N	z	Z		E	3
Abdominal	×	N	N		W	Z	z		z	S
intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	_	d	d .		Р	_ L	4		4	\$
Small Organs [1]	•	_	•		8	۵	Ь			\$
Nronatal Cephalic	۵	-	٩		ď	ı.	- L		- F	5
Adult Cephalic										
Cardine [2]	ı.	d	ı		Ь	L L	a			5
Transcsophageal (Cardine)										
Transesophageal (Non Carduse)										
Transectal	L									
Transvaginal										
Transurcthrai										
Intravascular								-		
Peripheral Vascular	4	2	Ь		a.	-	۰		2	5
Laparoscopic										
Musculo-aktictal Conventional	4	¥	١		d	Ь	<u>a</u>		a.	S.
Musculo-akeletal Superficial [3]	۵.	٥	4		a	d.	P		۰	\$
Other (Urological)										
The COST 132 nember is almendo										

The SC3123 probe is already cleared via K101605 and to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiae is Adult and Predistric

[3] Musculo Skeletal - Net Pre Block

[4] Compound of an E: B-M+PW-CW-CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) in Adult Cardiae for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

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SE3123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	prations	'	į	
Cinical Application	8	Σ	DWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined 4	Colar Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	۵	۵	ď		Ъ	Ь	Ь		Ь	Ş
Abdominal										
Intraoperative (Abdominal)									1	
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephaho										
Adult Cephalic	L									
Cardiac [2]										
Transesophageal (Cardiae)										
Transesophageal (Non Cardue)										
Transrectal	۵.	۵	2		a	2	2		٩	ьO
Transvaginal	۵	۵	2.		a.		٠		a.	ŝ
Transurethral										
fatravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial (3)										
Other (Urological)	٩	Ь	۵		Ь	Ь	ŀ		Ь	£
The SE3123 probe is already cleared via K132466										

N: New inducation; P. Previously cleared by FDA; E.Added under Appendix E.

[1] Small Organs includes Breast, Thyroid and Testicles [2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTl) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

77 3D/4D

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AL2442

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	rations			
Chrical Application	<u>a</u>	¥	PWD	СМО	Color Doppler	Amplitude Combined Doppler [4] IAD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	g.	•	ь		Ь	ď	ф		ь	9
Abdominal	۵	۵.	Ь		р	d	d		ъ	:2
intraoperative (Abdominal)			i							
Intraoperative Neurological										
Pediatric	£	s.	Ь	_	Ь	ل	د		P	5
Small Organs [1]	•	٠	d		ď	b	Ь		Р	ē
Neonatal Cephalic										
Adult Cephalic										
Curdiac [2]	d	ط	Ь		Ь	e.	Ь		٩	ıΑ
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
intravascular										
Peripheral Vascular	ı.	Ь	Ь		d,	ď.	9,		d.	m
Laparoscopic										
Musculo-skeletal Conventional	4	d	ď		d.	ط	G.		٩	u)
Musculo-skeletal Superficial [3]	a	d	۵		4	d	e.		£	ιĝ
Other (Urological)										
The AL2442 probe is aiready cleared via K132466									:	

N: New indication; P. Previously cleaned by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletai - Nerve Block

[5] Compound Imaging (Myview)
[6] Includes contrast (CnTI) in Adult Cardine for left ventricle opacification and visualization of the left ventricular endocurdial border [4] Combined modes are: B+M+PW+CW+CFM+PD

[7] 3D/4D

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SL3332

						Mode of Operations	DESCRIPTION OF THE PERSON OF T			
Clinical Application	В	Σ	QMd	CWD	Color	Amplitude	Š	Color Velocity	Harmonic	Other (specify)
	_				Doppler	Doppler (AD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	N	Z	N		z	×	N		Z	ī,
Abdominal	Z	Z	N		N	N	Z		z	10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Z	2	z		N	×	N		×	ιń
Small Organs [1]	N	N	2.		Z	7.	N		z	5
Neunatal Cephalic										
Adult Cephalic										
Cardine [2]	2	N	N		×	N	N		Z	ır.
Trans-sophageal (Cardiae)										
Transe-sophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral				-						
Intravascular										
Peripheral Vascular	×	Z	z		2	N	N		N	5
Гарагоясоріс										
Musculo-skeletal Conventional	z	¥	z		Z	N	N		ĸ	ıs
Musculo-skeletal Superficial [3]	×	z	z		N.	ž	R		z	ιņ
Other (Urological)										
The SL3332 probe is to be										

The SL3332 probe is to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E.Added under Appendix E. [1] Small Organs includes Breast, Thyroid and Testicles [2] Cardiac is Adult and Pediatric.
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CW+CFM+PD
[5] Compound Imaging (Mview)
[6] Includes contrast (CnTt) in Adult Cardiac for teft ventricle opacification and visualization of the left ventricular endocardial border

171 3D/4D

Prescription Use Only Per 21 CFR 801 Part D Concurrence of Center for Devices and Radiological Health (CDRH)

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SL1543

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						HOGO OF OPERATIONS	TRESON	i		
Clinical Application	8	×	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velority Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Орниватіс										
Fetal										
Abdominal	Ь	4	4		Р	а	Ь		Ь	10
Intraoperative (Abdominal)										
Intraoperative Neurological										,
Pediatric	۵	۵	د		d	d	d		. r	'n
Small Organs [1]	J	_	d		۵.	d	d		r	ş
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	£	ے	۵		ط	ь	ď		P	5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectat										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	А	Ь	Д.		۵.	۵	ď		۵	ŝ
Laparoscopic										
Musculo-skeletal Conventional	a	d	d		۵.	0.	٩		۵.	ю
Musculo-skeletal Superficial [3]	c.	d	d		۵	a.	d		۵	ΙĄ
Other (Urological)										
The SL1543 probe is already										

cleared via K132231

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E.

| 1| Small Organs includes Breast, Thyroid and Testicles | 2| Cardiac is Adult and Pediatric | 3| Musculo Skeletal - Nerve Block | 4| Combined modes are: B+M+FW+CW+CFM+PI) | 5| Compound Imaging (Mview) | 6| Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

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SL3323

						Mode of Operations	grations			
Chalcal Application	E)	×	DWG	CWD	Color Depater	Amplitude Combined Dopplet [4] (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	4	ď	Ь		ı u	4	d		F	
Intraoperative (Abdominat)	- E	a	d		٩	4] 4		ь	S
Intraoperative Neurological					-					
Pediatric	4	ь	4		Ь	d	4	!	"- r	2
Small Organs [1]	ı .	d	Ь		Ь	l l	٦		۴ ا	\$
Neonatal Cephalic	Ŀ	۵	d		Ь	d	. d		Ь	s
Aduli Cephalic										
Cardiac [2]	Z	N	2		2	Ж	z			
Transcraphageal (Cardiae)										
Transcsuplingeal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	3.	Н	đ		Ь	۵.	Δ.			\$
Laparoscopic										
Musculo-skeletal Conventional		4	P		P	d	G.			\$
Musculo-akeletal Superficial [3]	٥	٠	Ь		<u>.</u>	d	đ		[s
Other (Undogical)										
	l									

The SL3323 probe is already cleared via K101605 and to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E.

[1] Small Organs includes Bresst, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skekela] - Nerve Block

[4] Combined modes are: B+M+PW+CW+CPM+PD

[5] Computed Imaging IMrkew)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

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SL3235

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						moac of Operations	raciona			
Clinical Application	8	¥	OMd	CWD	Color	Amplitude Combined	Combined	Color Velocity	Harmonic	Other (specify)
					Doppier	Doppler (AD)	₹	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal										
Abdomina)										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	z	Z	×		×	ĸ	Z		2.	10
Small Organs [1]	z	z	N		z	N	X		7.	10
Neonatal Cephalic										
Adult Cephalic										
Cerdiac [2]										
Transcsuphageal (Cardiar)										
Transcxophageal (Non Cardiac)										
Transrectal										
Fransvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Z	Z.	N		Z	N	N		×	S
Laparoscopic										
Musculo-skeletal Conventional	z	Z	Z		Z	ĸ	N		z	s
Musculo-skeletal Superficial [3]	Z	z	Z		R	N	N		z	ŝ
Other (Urological)										
The SL3235 probe is to be										

the SL3Z33 probe is to be cleared via this submssion

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E. II Small Organs includes Breast, Thyroid and Testicles

(2) Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview) [6] Includes contrast (Cn71) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

7] 3D/4D

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SP2730

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						model of Operations	STREET STREET			
Clinical Application	£	Σ	Q.M.J	cwb	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ontrhalmic										
Fetal	×	z	Z	z	z	z	×		Z	
Abdominal	z	z	z	z	Z	z	z		z	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	z	z	z	×	Z	*	2		7.	
Small Organs [1]										
Neonatal Cephalic	z	×	z	z	×	×	N		z	
Adult Cephalic	z	Z	N	2	z	Z	N.		N	
Cardiac [2]	2	2	×	2	Z	Z	Z	N	N	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	z	Z	2	Z	R	N	И		Z	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]					1					:
Other (Urological)										
The SP2730 probe is to be cleared via this submission										

N. New indication; P. Previously cleared by FDA; E.Added under Appendix E.

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block | Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)
[6] Includes contrast (CnTt) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border
[7] 3D/4D

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SZMCW

						Mode of Operations	erations	!		
Clinical Application	æ	2	PWD	CWD	Color	Amplitude	Š	Color Velocity	Harmonic	Other (specify)
					coppie	(AD)	Ē.		68	
Ophthalmic										
Fetal										
Abdominal										
Introperative (Abdominal)										
Intraoperative Neurological										
Pediatric										i
Small Organs 1										
Neunatal Cephalic			}							
Adult Cephalic										
Cardiac [2]				1						
Transcsuphageal (Cardiac)										
Transesophageal (Non Cardine)								-		
Transrectal							٠			
Transvaginal										
Transurcthral										
Intravascular										
Peripheral Vascular				ď						
Laparuscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial (3)										
Other (Urological)										
The S2MCW probe is already										

The S2MCW probe is cleared via K132466

N: New indication; P. Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

(2) Cardiac is Adult and Pediatric (3) Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound imaging (Mytew)
[6] Includes contrast (CnTt) in Adult Cardiac for left ventricle opecification and visualization of the left ventricular endocardial border
[7] 3D/4D

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SSMCW

						Mode of Upgrations	rations.			
Cinical Application	н	×	DWD	CWD	Color	Amplitude	Š	Color Velocity		Orper (specify)
					Doppier	Doppler (AD)	Ξ	Mapping (TVM)	Imaging (TEI)	İ
Ophthalmic					_					
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Smull Organs [1]										
Nronatal Crphalic										
Adult Cephalic										
Cardiac [2]										
Transcrophageal (Cardiac)										
Transcsophageal (Non Cardiac)										
Transpectal										
Trunsvaginal		-								
Transurethral										
Intravascular										
Peripheral Vascular				d						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)										

The SSMCW probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA: E:Added under Appendix E. [1] Small Organs includes Breast. Thyroid and Testicles [2] Cardiac is Adult and Pedistric [3] Musculo Skeletal - Nerve Block.

|4| Combined modes are: B+M+PW+CW+CFM+PD |5| Compound Imaging (Mvirw) |6| Includes contrast (CnTI) in Adult Cardiac for left ventricle upacification and visualization of the left ventricular endocardial border

17] 3D/4D

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SB2C41

						gode of Operations	Taclons			
Chaical Application	e e	Σ	PWD	CWD	Color Doppler	Amplitude Combined Doppler [4] (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal		۵.	d		Ь	۵	۵		Ь	5.7
Abdominal	۵.	g,	۵		Ь	۵.	a		А	5,7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethrat										
Intravascular										
Peripheral Vascutar										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)										
The SB2C41 probe is already										

the SECCHI proof is chared via K132231

N: New indication; P. Previously cleaned by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

|2| Cardiac is Adult and Pediatric |3| Musculo Skrhetal - Nerve Block |4| Combined modes are: B+M+PW+CW+CFM+PD |5| Compound Imaging | Mvirw| |6| Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

17| 3D/4D

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SHFCW

						The second	10000			
Clinical Application	8	X	DWP	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)									-	
Transcsophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				д						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)										
The SHFCW probe is already										

The SHFCW probe is: cleared via K132466

N: New Indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

|2| Cardiac is Adult and Pediatric |3| Musculo Skeletal - Nerve Block |4| Combined modes are: B+M+PW+CW+CFM+PD |5| Compound Imaging | Mview| |6| Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

71 3D/4D

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ST2612

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	prations			
Clinical Application	œ	Σ	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Onhthalmic										
Fetal										
Abdominal		L								
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neunatal Cephalic										
Adult Cephalir										
Cardiac [2]										
Transesophageal (Cardiac)		d		d	d	ď]	ı,	ь	ç
Transesophageal (Non Cardiae)										
Transrectal										
Transvaginal										
Transurethral			,							
intravascular		L								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)										
The ST2612 probe is already										

cleared via K132466

N: New indication; P. Previously cleared by FDA; E.Added under Appendix E.

[1] Small Organs includes Breast, Thyroid and Testickes

[2] Cardiac is Adult and Pediatric

[3] Musculo Skrietal - Nerve Block

14 Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)
[6] Includes contrast (Cn71) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

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IOT342

						provide of A polarious	1			
Clinical Application	8	Σ	QMd	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
				1						
Ophthalmic										
Fetal										
Abdominal	-	d	d		d	d	d		Ь	ç
Intraoperative (Abdominal)	۵	c.	۵		d	d	d	:	d	3
Intraoperative Neurological										
Pediatric	Н	d	đ		Ь	d	d		b	ŝ
Small Organs [1]	d		d		Ь	4	d		P	÷
Neonatal Ceptudic										
Adult Cephalic										
Cardiac [2]		ł								
Transesophageal (Cardiae)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal		l								
Transurethral										
Intravascutar										
Peripheral Vascular	А	a	Ъ		Ь	۵	ď		P	5
Laparoscopic										
Musculo-skeletal Conventional	۵	a.	4		ď	a	ď		d	is
Musculo-skelcial Superficial [3]	۵.	a	a		•	a .	4		d	25
Other [Urological]										
The IOT342 probe is already cleared via K132466							•			

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric [3] Musculo Skeletal - Nerve Block

|4| Combined modes are: B+M+PW+CW+CFM+PD |5| Compound Imaging ||Wview| |6| includes contrast (CnTl) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border.

7] 3D/4D

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